1 2 3 4 5 6 7 8 9 10	Brian C. Swanson (pro hac vice) brian.swanson@bartlitbeck.com Katherine M. Swift (pro hac vice) katherine.swift@bartlitbeck.com BARTLIT BECK LLP 54 West Hubbard Street Chicago, IL 60654 Telephone: 312.494.4400 Facsimile: 312.494.4440 Alex J. Harris (pro hac vice) alex.harris@bartlitbeck.com Gabriel J. Levin (SBN 330163) gabe.levin@bartlitbeck.com BARTLIT BECK LLP 1801 Wewatta Street, Suite 1200 Denver, CO 80202 Telephone: 303.592.3100 Facsimile: 303.592.3140				
12	Attorneys for Defendant Walgreen Co. (Additional counsel listed on signature page)				
13	UNITED STATES DISTRICT COURT				
14	NORTHERN DISTRICT OF CALIFORNIA				
15					
16	CITY AND COUNTY OF SAN FRANCISCO, et al.	Case No. 3:18-cv-07591-CRB			
17 18	Plaintiffs,	DEFENDANTS' OBJECTIONS TO THE DECLARATION OF CRAIG MCCANN			
19	vs.	CRAIG WECANN			
20	PURDUE PHARMA L.P. et al.				
21	Defendants.				
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Defendants Cephalon, Inc.; Teva Pharmaceuticals USA, Inc.; specially appearing Teva Pharmaceutical Industries Ltd.; Watson Laboratories, Inc.; Actavis LLC, Actavis Pharma, Inc., f/k/a Watson Pharma, Inc.; Actavis Elizabeth LLC; Actavis Mid Atlantic LLC; Warner Chilcott Company, LLC; Actavis South Atlantic LLC; Actavis Totowa LLC; Actavis Kadian LLC; Actavis Laboratories UT, Inc., f/k/a/ Watson Laboratories, Inc.-Salt Lake City; and Actavis Laboratories FL, Inc., f/k/a Watson Laboratories, Inc.-Florida (collectively, the Teva, Cephalon, and Actavis Generic Entities); Allergan Finance, LLC; Allergan Sales, LLC, and Allergan USA, Inc., and Specially Appearing Defendant Allergan plc (collectively, the Allergan Defendants); Anda, Inc; and Walgreen Co., (altogether, the Defendants) hereby submit their objections to the Trial Declaration of Craig McCann, PH.D., CFA ("McCann Declaration"). Defendants object to several portions of Dr. McCann's testimony.

I. **Dr. McCann's Undisclosed Opinions**

Defendants object to several portions of Dr. McCann's testimony because they were not disclosed in his reports as required under Federal Rule of Civil Procedure 26. Rule 26(a)(2) requires that an expert report must contain, among other things, "(i) a complete statement of all opinions the witness will express and the basis and reasons for them; (ii) the facts or data considered by the witness in forming them; [and] (iii) any exhibits that will be used to summarize or support them." When an expert fails to make these required disclosures, Rule 37(c) prohibits the use of the undisclosed information unless the failure was substantially justified or harmless. Fed. R. Civ. P. 37(c). See Nortek Air Solutions, LLC v. Energy Lab Corp., No. 14-cv-02919-BLF, 2016 WL 3856250, at *7 (N.D. Cal. Jul. 15, 2016) ("If [an] expert's testimony is not found in his or her expert report, that evidence will not be allowed at trial."); see also PersonalWeb Techs. LLC v. Int'l Bus. Machines Corp., No. 16-CV-01266-EJD, 2017 WL 8186294, at *4 (N.D. Cal. July 25, 2017) (precluding expert testimony where expert report had identified only "generic system" requirements" and failed to identify "particular examples" or to "specifically address"

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defendant's surveys).

This Court's Guidelines for Civil Jury Trials recognize the importance of the Federal Rules' disclosure requirements—stating that "[a] recurring problem in trials is . . . expert witnesses trying to go beyond the scope of their expert reports on direct examination." *See* Guidelines for Civil Jury Trials Before Judge Charles R. Breyer, April 2, 2019 at 6. Dr. McCann's failure to disclose is neither justified nor harmless as many of his new opinions deviate significantly from what he disclosed in his expert reports. This Court has excluded expert opinions disclosed for the first time in rebuttal. *See* Dkt. 1276 ("Defendants cannot fairly respond to a new analysis disclosed for the first time in rebuttal."). This is much worse. Defendants certainly cannot fairly respond to a new analysis disclosed for the first time during trial, just days before the expert's expected testimony.

a. Walgreens

McCann's Opioid Distributor Flagged Shipment Summary, Paragraphs 13–17

Dr. McCann's flagged shipment summary shows the percentage of Walgreens' opioid shipments that were flagged by one of seven algorithms. *See* McCann Declaration ¶¶ 13–17. But Dr. McCann has never before disclosed the flagged shipment summary contained in his trial declaration. And McCann's new analysis is not based on a method disclosed by any subject-matter expert in this case. Plaintiff's DEA expert Jim Rafalski provided Dr. McCann with seven *different* methods for flagging orders, based largely on "recurrent" flagging—an instruction to Dr. McCann to flag *every order* after the first flagged order from a pharmacy, regardless of whether any subsequent order independently flagged on one of the algorithms. The recurrent flagging assumption led to flagging the vast majority of orders shipped, rendering the results so voluminous that Defendants never could have examined Dr. McCann on more than a small fraction of the flagged orders. Dr. McCann's declaration adds a brand new "non-recurrent" flagging analysis that removes the "recurrent" flagging instruction, and flags "only the transaction that triggers the flag."

McCann Declaration ¶ 13.

The new analysis contains dramatically different results than the analysis disclosed in McCann's expert report. As shown for Walgreens' self-distribution in the tables below, the percentage of dosage units flagged under certain methods drops by over 95%.

McCann's Recurrent Distribution Flagging, as Disclosed in his						
Expert Report						
(McCann Report, Appendix 9 at 2169–2231)						
Method	Method	Method	Method	Method	Method	Method
1	2	3	4	5	6	7
86.60%	19.60%	22.00%	10.60%	66.80%	93.40%	90.60%

McCann's Non-Recurrent Distribution Flagging, as First Disclosed in						
his Declaration						
(McCann Declaration at 7–8)						
Method	Method	Method	Method	Method	Method	Method
1	2	3	4	5	6	7
4.30%	19.60%	6.70%	3.50%	24.50%	67.40%	25.80%

Moreover, McCann did not even provide the underlying code explaining how he calculated his new results. *See id.* Defendants therefore have no way of determining how he arrived at his new numbers, much less of verifying their accuracy.

Dr. McCann has provided no justification for changing his analysis in the middle of trial, and his late disclosure is not harmless as Defendants were deprived of the ability to test his work during expert discovery. *See* Dkt. 1276 (striking certain opinions of Drs. Keyes and Waldman because Defendants could not "fairly respond to a new analysis disclosed for the first time in rebuttal").

Furthermore, there is no foundation for Dr. McCann's testimony on this new analysis, as it is not based on any subject-matter expert's testimony. Even if Dr. McCann were limited to his previously disclosed "recurrent" flagging analysis, his testimony would necessarily need to follow that of Mr. Rafalski, the DEA expert who created the algorithms that Dr. McCann relies on. Dr. McCann's Flagged Shipment Summary should be stricken

for these reasons.

Portions of Tables on Pages 41–42

Dr. McCann's tables on pages 41 and 42 include columns that apply his undisclosed "non-recurrent" flagging analysis described above. *See* McCann Declaration at 41 (column six showing "Distributors Non-Recurrent Red Flag Percent of MMEs); *id.* at 42 (column three showing "Defendant Dispensers Non-Recurrent Red Flagged Opioid Prescriptions). These specific columns should be stricken for the same reasons.

Paragraphs 64–66 & Plaintiff's Exhibit 29849

Paragraphs 64–66 of Dr. McCann's declaration provide analysis comparing the number of target drug opioid prescriptions filled at Walgreens versus the number of Target Drug Checklists completed. *See* McCann Declaration ¶ 64–66; P-29849. This analysis was not included in Dr. McCann's expert report, so Walgreens was not able to test the analysis during expert discovery. While Plaintiff disclosed P-29849 with its 1006 summaries, this Court has emphasized that Rule 26 requires that "any exhibits to be used as summary of or support for [expert] opinions be included in the report." *See* Guidelines for Civil Jury Trials Before Judge Charles R. Breyer, April 2, 2019 at 6. Neither McCann's opinions in paragraphs 64–66 nor his summaries of those opinions contained in P-29849 were disclosed in his expert report. Walgreens cannot fairly respond to or verify the accuracy of these opinions disclosed for the first time during trial. Dr. McCann's testimony on this matter should be stricken accordingly.

Paragraph 55, P-29850

Walgreens' Suspicious Control Drug Reports and calculates the percentage of Walgreens's shipments that were in its Suspicious Control Drug Order Reports. *See* P-29850. This analysis was not included in any of Dr. McCann's expert reports, so Walgreens was unable to test McCann's analysis during expert discovery. While Plaintiff disclosed P-29850 with its 1006 summaries, this Court has acknowledged that Rule 26 requires that "any exhibits

to be used as summary of or support for [expert] opinions be included in the report." *See* Guidelines for Civil Jury Trials Before Judge Charles R. Breyer, April 2, 2019 at 6. Neither McCann's opinions in paragraph 55 nor his summaries of those opinions contained in P-29850 were disclosed in his expert report. Walgreens cannot fairly respond to or verify the accuracy of these opinions disclosed for the first time during trial. Dr. McCann's testimony on this matter should be stricken.

Paragraph 71, P-29876

Walgreens objects to Plaintiff's exhibit 29876 cited in paragraph 71 for lack of disclosure. P-29876 summarizes CURES data and provides a comparative analysis of prescriptions written by selected prescribers and filled at Walgreens and non-Walgreens stores. Neither this summary nor the underlying source material was disclosed in any of Dr. McCann's reports. Plaintiff did disclose P-29876 in its 1006 summaries, but, again, this Court has acknowledged that Rule 26 requires that "any exhibits to be used as summary of or support for [expert] opinions be included in the report." *See* Guidelines for Civil Jury Trials Before Judge Charles R. Breyer, April 2, 2019 at 6. Walgreens cannot fairly respond to or verify the accuracy of these opinions disclosed for the first time during trial, just days before Dr. McCann is set to testify. Dr. McCann's testimony on this matter should be stricken.

Additional Undisclosed Opinions and Exhibits

Walgreens also objects to several other undisclosed summaries cited in Dr. McCann's declaration. *See* McCann Declaration ¶ 40 (citing P-29878 which for the first time summarizes opioids distributed by all distributors to Walgreens by drug); *id.* ¶ 69 (citing 29874 which summarizes CURES data setting out the number of prescriptions, patients and dosage units, and MME in San Francisco and was not included in McCann's reports); *id.* ¶ 70 (citing P-29875 which summarizes CURES data that shows the opioid market share of selected San Francisco pharmacies and was not included in any of Dr. McCann's expert reports); *id.* ¶ 72 (citing P-29877 which summarizes for the first time

CURES data that shows the total number of prescriptions filled, the average number of prescriptions filled monthly, the total dosage units of prescriptions filled, and the average dosage units of prescriptions filled monthly, for selected pharmacies). While Plaintiff disclosed these exhibits with its 1006 summaries, this Court has acknowledged that Rule 26 requires that "any exhibits to be used as summary of or support for [expert] opinions be included in the report." *See* Guidelines for Civil Jury Trials Before Judge Charles R. Breyer, April 2, 2019 at 6. Walgreens had no opportunity to respond to or verify the accuracy of these summaries during expert discovery. They should be stricken from Dr. McCann's testimony.

b. Teva, Cephalon, Actavis Defendants

Non-flagged Transactions Attributed to Manufacturers

Dr. McCann's trial declaration asserts a never-before-expressed opinion related to "non-recurrent" flagged transactions that he attributes to the manufacturing defendants. See McCann Decl. ¶¶ 79-80. Apparently realizing that the results of his "recurrent" flagging method are unsupportable on their face because they simply assume that all orders that follow a flagged order should be automatically flagged forever, Dr. McCann includes two new demonstratives (CT4-MCCANN-DEMO-0016 and CT4-MCCANN-DEMO-0017) which purportedly "illustrate[] the results of attributing the flagged transactions to Manufacturers on a recurrent and non-recurrent basis." See McCann Decl. ¶¶ 79-80, emphasis added.

The difference in percentage of flagged transactions when using the recurrent approach that was used in his expert reports compared to the newly disclosed non-recurrent approach is stark. The recurrent flagging methodology led to most of the orders reviewed being flagged using each of Dr. Rafalski's methods. *See* McCann Decl. ¶ 79. And because most of the orders were flagged, the number "attributed" to the manufacturing defendants was significant. *See* McCann Decl. ¶ 79. For example, Dr. McCann's recurrent approach using Dr. Rafalski's Methodology 1 flagged 94.3% of the total dosage units of opioids

dispensed by retail and chain pharmacies in San Francisco between 1996-2018, while the non-recurrent modification to Methodology 1 flags just 5.6% of the total dosage units. A fluctuation from 94.3% to 5.6% reveals the untenable nature of his "recurrent basis" methodology, and prejudices manufacturers' ability to cross examine Dr. McCann. Dr. McCann should not be permitted to try to fix this patent defect in his methodology long after expert discovery has closed with an entirely new methodology disclosed on days before he is set to testify. In the throes of trial, Defendants cannot determine Dr. McCann's qualifications to use this new methodology, whether the methodology is reliable, and how that methodology was applied. The "non-recurrent" flagging analysis should be stricken from Dr. McCann's declaration.

c. Anda, Inc.

i. Undisclosed Supply/Market Share

For the first time in his Trial Declaration, Dr. McCann presents new calculations relating to the volume of dosage units of opioids Anda shipped to its customers in San Francisco. *See* Revised McCann Declaration ¶ 10. Although the Declaration does not provide a detailed explanation of the changes, and thus Anda has not had a full and fair opportunity to analyze the changes during the expert discovery period, it appears as though Dr. McCann has manipulated the products considered as well as the nature of the customers included in the analysis to increase the figures.

For example, in his report issued according to the Court's expert discovery deadlines, Dr. McCann calculates two different market share figures. The first is at Table 28, where Dr. McCann reports his calculation of Anda's sales of 12 drugs, excluding buprenorphine and methadone—opioid products used for treatment of OUD, to chain and retail pharmacies only from 2006-2014. The result, as reported by Dr. McCann is that Anda shipped 2,636,092 dosage units or **1.38%** of all the dosage units of these 12 products shipped to San Francisco pharmacies. McCann Report at pg. 48.

Dr. McCann also included in Appendix 9 to his original report, a market share

calculation, again limited to 12 opioid products so as not to include the two treatment drugs, but this time his calculation includes shipments to all dispensers in San Francisco, i.e. not limited to chain and retail pharmacies. McCann App'x 9 at pg. 49. Dr. McCann reported that Anda shipped 2,659,892 dosage units or **0.96%** of all dosage units shipped for the 12 products to all dispensers in San Francisco. *Id*.

Now, for the first time in his Declaration, Dr. McCann presents yet another market share calculation, but in this calculation Dr. McCann has inexplicably included in the analysis the opioid use disorder treatment products that were previously excluded. The result—the number of dosage units Anda shipped to chain and retail pharmacies increased to 4,074,542 or 2% of the market share. Dr. McCann offers no explanation for this shift in product focus—where in all prior formulations he did not include those treatment drugs. Dr. McCann should not be permitted to "goose" the numbers, particularly where Anda has relied upon his prior calculations in its briefing and opening comments to this Court. Nor is it an adequate solution that Anda spend its limited trial time to cross-examine Dr. McCann on this previously undisclosed calculation.

ii. Undisclosed Flagging Methodology

As with Walgreens, Dr. McCann's Trial Declaration adds a previously undisclosed "flagging methodology" for Anda as well. *See* Revised McCann Declaration ¶¶ 12-16. For the reasons set forth by Walgreens above, those new methodologies have no support either in Dr. McCann's Declaration or supporting materials. Dr. McCann's Flagged Shipment Summary should be stricken for these reasons.

iii. Additional Analyses

Dr. McCann likewise includes in his Trial Declaration, exhibits and "demonstratives" a number of calculations involving shipments made by registrants outside of San Francisco who the People apparently intend to argue have some connection to Anda's conduct in San Francisco. There is no basis for such a leap and no foundation in Dr. McCann's report to explain any such connection. Therefore, any such testimony,

including the following materials should be precluded from trial:

P-04747; P-29854; P-29864; P-29855; P-29865; P-29865; P-29865; P-29866; P-29868; P-29868; P-29869; P-29860; P-29861; P29862; P-29863.

II. <u>Improper Grouping of Distinct Corporate Entities</u>

Dr. McCann's trial declaration is rife with objectionable groupings of distinct corporate entities. Throughout his trial declaration, Dr. McCann refers to "Manufacturer Defendants" without explicitly defining the term. One is left to assume that Manufacturer Defendants means "Actavis," "Teva," "Allergan," and "Cephalon" since those are the only names under the "Manufacturer" columns of the tables in Dr. McCann's declaration. See McCann Decl. ¶ 75. However, the each of these four purported manufacturers are not defined. Use of the term "Actavis" is particularly problematic in this regard because there are 11 Actavis Generic Defendants in this case, and it's unclear if the reference to "Actavis" in Dr. McCann's declaration encompasses all of these defendant entities, some of them, or none of them. Further, Dr. McCann simply states that he used NDCs that were provided to him in discovery responses, but nowhere identifies what the NDCs are and to which specific defendants (or non-defendant) entity they are attributed. Dr. McCann cannot be allowed to attribute transactions to the "Manufacturer Defendants" when his use of vague and ambiguous terms fails to specifically identify the specific defendant entities involved. Defendants respectfully request that the portion of his declaration referencing "Actavis," "Teva," "Allergan," and "Cephalon" be stricken.

III. <u>Improper Reference to Table 20</u>

Dr. McCann also improperly references a Table 20 that does not appear in his declaration. Specifically, Dr. McCann states in his trial declaration, "In the tables below (Supplemental Tables 17, 26, 20, and 61 in my Second Supplemental Report), I summarize the Manufacturer Defendants of the 12 drugs...." *See* McCann Decl. ¶ 75. However, the "tables below" are Supplemental Tables 17, 26, 60, and 61. Thus, Dr. McCann's reference to Table 20 is unclear, and Defendants are left to assume that this is actually a reference to

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Table 60. If only a typographical mistake, Dr. McCann should update his declaration to correct this error. However, to the extent Dr. McCann is intending to reference a Supplemental Table 20 which has not been previously provided to Defendants, this reference and any testimony that relies upon this Table 20 should be stricken from the declaration as outside the scope of Dr. McCann's expert opinions.

These are the objections that Defendants have been able to identify in the limited time provided by the parties' declaration objection process. Along with a 44-page declaration, Dr. McCann attached over 150 exhibits, including nearly 30 that are brand new. Defendants reserve the right to add new objections, including after McCann testifies, to the extent we continue to identify previously undisclosed analyses.

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2	Respectfully submitted,
3	/s/ Katherine M. Swift
4	Brian C. Swanson (pro hac vice) brian.swanson@bartlitbeck.com
5	Katherine M. Swift (pro hac vice) kate.swift@bartlitbeck.com
6	BARTLIT BECK LLP 54 West Hubbard Street
7	Chicago, IL 60654 Telephone: 312.494.4400
8	Facsimile: 312.494.4440
9	Alex J. Harris (pro hac vice) alex.harris@bartlitbeck.com
10	Gabriel J. Levin (SBN 330163) gabe.levin@bartlitbeck.com
11	BARTLIT BECK LLP 1801 Wewatta Street, Suite 1200
12	Denver, CO 80202
13	Telephone: 303.592.3100 Facsimile: 303.592.3140
14	Charles J. Stevens (SBN 106981) cstevens@gibsondunn.com
15	Joshua D. Dick (SBN 268853) jdick@gibsondunn.com
16	Kelsey J. Helland (SBN 298888) khelland@gibsondunn.com
17	GIBSON DUNN & CRUTCHER LLP 555 Mission Street, Suite 3000
18	San Francisco, CA 94105 Telephone: 415.393.8200
19	Facsimile: 415.393.8306
20	Attorneys for Defendant WALGREEN CO.
21	
22	/s/ Collie F. James, IV Collie F. James, IV (S.B. #192318)
23	Theodore Dayno (S.B. #286708)
24	MORGAN, LEWIS & BOCKIUS LLP 600 Anton Blvd., Suite 1800
25	Costa Mesa, CA 92626 Telephone: (714) 830-0600
26	collie.james@morganlewis.com theodore.dayno@morganlewis.com
27	
28	
	11

Zachary Hill (S.B. #275886) 1 Mark Allen (S.B. #293155) MORGAN, LEWIS & BOCKIUS LLP 2 One Market, Spear Street Tower 3 San Francisco, CA 94105-1596 Telephone: (415) 442-1000 zachary.hill@morganlewis.com 4 mark.allen@morganlewis.com 5 Wendy West Feinstein (pro hac vice) Katherine A. Vaky (pro hac vice) 6 MORGAN, LEWIS & BOCKIUS LLP 7 One Oxford Centre, 32nd Floor Pittsburgh, PA 15219-6401 8 Telephone: (412) 560-7455 wendy.feinstein@morganlewis.com 9 katherine.vaky@morganlewis.com 10 Attorneys for Defendants Cephalon, Inc.; Teva Pharmaceuticals USA, Inc.; specially appearing Teva 11 Pharmaceutical Industries Ltd.; 12 Watson Laboratories, Inc.: Actavis LLC, Actavis Pharma, Inc., f/k/a 13 Watson Pharma, Inc.; Actavis Elizabeth LLC; Actavis Mid Atlantic LLC; Warner Chilcott Company, LLC; 14 Actavis South Atlantic LLC; Actavis 15 Totowa LLC; Actavis Kadian LLC; Actavis Laboratories UT, Inc., f/k/a/ Watson Laboratories, Inc.-Salt Lake 16 City; and Actavis Laboratories FL, 17 Inc., f/k/a Watson Laboratories, Inc.-Florida 18 19 s/ Jaime Dorenbaum_ Jaime Dorenbaum 20 FOLEY & LARDNER LLP 555 California Street, Suite 1700 21 San Francisco, CA 94104-1520 Telephone: (415) 434-4484 22 Facsimile: (415) 434-4507 idorenbaum@foley.com 23 James W. Matthews (pro hac vice) 24 Ana M. Francisco (pro hac vice) Katy E. Koski (pro hac vice) 25 FOLEY & LARDNER LLP 111 Huntington Avenue 26 Boston, MA 02199-7610 Telephone: (617) 342-4000 27 Facsimile: (617) 342-4000 imatthews@foley.com 28 12

1	francisco@foley.com kkoski@foley.com
2	·
3	Gregory N. Heinen (pro hac vice) Kristina J. Matic (pro hac vice) 777 E. Wisconsin Avenue
4	Milwaukee, WI 53202
5	Tel: (414) 271-2400 Fax: (414) 297-4900
6	gheinen@foley.com kmatic@foley.com
7	Attorneys for Defendant Anda, Inc
8	/s/ Zachary A. Ciullo
9	Nicole K. Smith (S.B. #330384) KIRKLAND & ELLIS LLP
10	555 California Street San Francisco, CA 94104
11	Telephone: (415) 439-1400 Facsimile: (415) 439-1500
12	nicole.k.smith@kirkland.com
13	James F. Hurst, P.C. (pro hac vice)
14	Hariklia Karis, P.C. (<i>pro hac vice</i>) Zachary A. Ciullo (<i>pro hac vice</i>) KIRKLAND & ELLIS LLP
15	300 North LaSalle
16	Chicago, IL 60654 Telephone: (312) 862-2000
17	Facsimile: (312) 862-2200 james.hurst@kirkland.com
18	hkaris@kirkland.com zac.ciullo@kirkland.com
19	Attorneys for Defendants Allergan
20	Finance, LLC, Allergan Sales, LLC, and Allergan USA, Inc., and specially
21	appearing defendant Allergan plc ¹
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27	Specially Appearing Defendant Allergan plc, formerly known as Actavis plc and is now known as Allergan Limited, does not waive but rather expressly preserves its
28	objection to the Court's personal jurisdiction over it.
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